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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,112	05/06/2004	Jaime Simon	61350C	8566

109 7590 07/19/2007
THE DOW CHEMICAL COMPANY
INTELLECTUAL PROPERTY SECTION,
P. O. BOX 1967
MIDLAND, MI 48641-1967

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
07/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/840,112	SIMON ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/25/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The claims 1-23 are pending and presented for examination.

Response to Arguments

2. Applicant's arguments filed on May 11, 2007 with respect to the rejection(s) of claims 1-23 under USC 102 have been fully considered and are not persuasive. However, the Motoki Yonekawa et al. (JP H10-130154) rejection is withdrawn. To make better flow, upon further consideration, a new ground(s) of rejection is made as follow.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims because the specification, while being enabling for treating certain fluid mal-distribution state in a host using a water-absorbent polymer as claimed, does not reasonably provide enablement for preventing all the possible fluid overload states or patients suffering from mal-distribution of fluid using a water-absorbent polymer as claimed.

Attention is directed to Inre Wands, 8 USPQ 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls) at 547 court recited eight factors:

1) The Nature of the invention:

The instant invention is drawn to a method of treating a fluid mal-distribution state in a host, comprising administering the instant composition as recited in claim 1.

2) The state of the prior art:

As the state of art recognizes, there are various forms of overload states or patients suffering from mal-distribution of fluid result form a variety of conditions. This process, in turn produces symptoms of diabetes, physiological changes of aging, nocturia, pre-menstrual syndrome, some forms of hypertension, obesity, and chronic renal insufficiency etc thus preventing or treating will include screening in vitro and vivo to determine the effect of the water-absorbent polymer composition on the specific mal-distribution of fluid in a patient. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any pharmaceutically effective amount of a water-absorbent polymer regimen on its face. However, there is no single pharmaceutical preparation/treatment available, which treats or reduces all symptoms of fluid mal-distribution state in a host and such inflammation modulating treatments are not without potential side effects. The instant claim invention is highly unpredictable as discussed below:

Thus, in the absence of showing of correlation between all the conditions associated with of fluid mal-distribution state in a host claimed as capable of being treated by the composition of the instant claims, one of ordinary skill in the art is unable to fully predict possible results from the administration of the water-absorbent polymer composition due to the unpredictability of the role of nocturia and hypertension diseases for example.

3) The relative skill of those in the art:

The level of one of ordinary skill in the fluid mal-distribution state caused by abnormal physiological order/functions is considered a master level and is quite substantial. Yet, even at such a high level of skill, there would be required undue experimentation on the part of the skilled artisan in order to practice the invention.

4) The predictability of the art:

The art pertaining to the treatment of fluid mal-distribution state remains highly unpredictable. The specification does not provide any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant water-absorbent polymer composition. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18,24 (CCPA 1970).

5) The breadth of the claims:

Applicant's assertion that the inventive water-absorbent polymer composition would be useful for treating/preventing mal-distribution of fluid does not commensurate with the

scope of the objective enablement, especially in view of the high degree of unpredictability and the limited working examples.

6) The amount of guidance:

The specification only exemplifies few examples such as a treating for nocturia and hypertension, see examples 4 and 5. The specification neither fails to show complete prevention nor fails to include any other fluid mal-distribution state in the treatment, which may be caused by abnormal physiological activity.

The specification provides lack of evidential support substantially where any skilled artisan cannot clearly understand how the claimed invention is achieved at the time of the invention with the information provided and thus, the claims are considered not enabled with the information given.

7) The existence of working examples:

As stated above, the working examples use only water-absorbent polymer. Both specification and disclosure fails to provide adequate representation regarding the conclusion of the efficacy of water-absorbent composition to treat the fluid mal-distribution state in a host.

8) *The quantity of experimentation necessary*:

Since the efficacy of water-absorbent polymer composition treating fluid mal-distribution state mentioned above cannot be predicted from a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighted together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to use the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being obvious over Berger et al. (US 4,470,975) in view of Samejima et al. (EP 0077956) and Thompson et al. (US 5,004,603) together.

The claims are directed towards a method for treating or removing fluid from the intestinal tract of a host comprising enteric-coated, non-toxic, water-absorbing polymer as active ingredient, wherein the water-absorbing polymer is capable of absorbing at least 10-40 times its weight in physiological saline and wherein the polymer is formed of polymerized acrylic acid monomers or salts thereof or the polymer is a polysaccharide.

Berger discloses a composition and method of removing fluid or edema by diverting water elimination from the renal route to the gastrointestinal route, and removing excess water from the body by the gastrointestinal tract of an animal by administrating to said animal dextrans: a polysaccharide that is a polymer made of monomers of carbohydrate moieties in form of gel grains (see abstract, column 1, line 54-56 and column 10, lines 5-30). Berger also discloses a composition and method for treating abnormal excess accumulation of fluid within the body, such as congestive heart failure, cirrhosis of the liver, nephrosis and other renal diseases associated with fluid retention in said animal (see column 1, lines 63+). Berger also discloses the insoluble cross-linked polysaccharide polymer may be ingested by the patient and during passage

of these substances through the digestive system, water is absorbed or bound tremendously and finally along with bound water, urea in the lumen of the gastrointestinal system is then eliminated by passage from the alimentary canal in the normal manner. Patients with renal failure cannot excrete all of the fluid and electrolytes needing excretion, total body levels of sodium, potassium, calcium, phosphate, chloride, water and various traces minerals ingested in their diet are usually higher than normal. Exclusive fluid retention and abnormal hormonal production causes hypertension. The conventional treatment for diseases of this nature is periodic hemodialysis. Consequently, patients on renal dialysis usually are receiving numerous medications to control their blood pressure, hormonal status, fat levels, and serum chemistries. Thus it has been found that certain insoluble hydrophilic, cross-linked polysaccharides are useful pharmaceutical agents for the treatment of abnormal excess accumulation of fluid within the body, such as, congestive heart failure, cirrhosis of the liver, nephrosis, and other renal diseases associated with fluid retention (see column 1 and 2).

Applicant's claims differ in that because they require a method for treatment of excess fluid by directly administering to the intestinal tract of the host and polymerizing a monomer comprising acrylic acid or salts thereof in removing fluid or edema when Berger is taken in view of Samejima with Thompson, because, Samejima with Thompson together discloses a method for removing fluid or edema from the gastrointestinal tract of an animal by administering an enteric-coated microcapsule comprising water-swellable polymeric material in the core and the monomers of acrylic acid polymer is capable of absorbing at least 10 times its weight of fluid.

Samejima discloses an enteric-coated microcapsules comprising water-swellable polymer material in the core, said polymer is capable of absorbing water (1.2-1.5 times its weight, see

page 5, lines 10-22, page 6, line 9 and page 27 lines 1-5). Patent '956 also discloses the composition in the form of enteric microcapsule is capable of releasing easily the active component in intestinal tract and maintain the active component (core material) effectively in the stomach (see page 2, lines 16-20). The patent '956 also discloses that the composition is in granule formulation (see page 22, line 1-10).

Thompson discloses a method of administering a composition to ruminants, such feeding composition comprising polymers derived from monomers such as (meth)acrylic acid and (meth)acrylamide that is capable of absorbing water and swell by a factor (w/w) of at least 10-50 times its weight (see col 3, lines 35-60).

When these references are taken together, one would have been motivated to make a composition comprising of water-absorbent polymer and use the composition in the form of tablet or capsule for treatment of excess fluid in the intestinal tract to maximize therapeutic efficacy. By coating the composition with enteric polymer, one of ordinary skill would expect to obtain an intact and therefore effective composition for removing excess fluid from the body--- without the enteric coating, the polymer in the composition (e.g. polysaccharides) would be more susceptible to degradation by the acidic environment of the stomach (see Berger patent col 4, line 55-60 for the suggestion or motivation for enterically coating the composition). As suggested by cited reference, one would have reasonably expected successful removing of excess fluid in a body by directly administering an effective amount of a water-absorbent polymer to the intestinal tract of the host because the effectiveness, extra benefits (i.e., absorbing at least 10-40 times its weight in physiological saline) and safety are already well proven and are well suggested by latter reference cited.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities),and pertinent to the problem which applicant concerns about. MPEP 2141.01 (a).

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 11-14 of U.S. Patent No. 6,908,609. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are directed to a method for treating fluid overload states in a host by directly delivering an effective amount of an enterically coated water-absorbent polymer to the intestinal tract wherein the polymer absorbs at least about 20 times its weight in physiological saline. Both the instant application and US 6,908,609 involves a method for treating a fluid mal-

distribution state in a host, comprising the step of directly administering to the intestinal tract an effective amount of a water-absorbent polymer. While the issued claims are not anticipatory in the sense of claim for claim, the issued claims and the examined claims are directed to the same subject matter and are properly included in the rejection because they are patentably distinct from each other.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr